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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,502	02/22/2002	Jeffrey L. Cleland	146392000500	8669

25226 7590 07/09/2008
MORRISON & FOERSTER LLP
755 PAGE MILL RD
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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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07/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/080,502	Applicant(s) CLELAND ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,9-11,14-16,19-22,44,48,55-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,9-11,14,16,19-22,44,48,56-58,60-63,66-73,75-81 and 84-88 is/are rejected.
- 7) ☒ Claim(s) 4,15,55,64,65,82 and 83 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04082008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendment filed 04/08/2008.

The rejections under 35 USC 112, first paragraph, for written description and scope of enablement, as well as the claim objections are withdrawn in view of applicant's amendments.

The following rejection is made after a supplemental examination prior to a decision on patentability:

Claim Objections

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 26 already sets out the amount of hydrophobic solvent. Claim 14 therefore fails to further limit the invention. Correction is requested.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5,6,9-11, 14, 16, 19, 20-22, 44, 48, 55-58, 60- 63, 66-73, 75-81, 84-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over PCT/US97/23659 (Brodeck et al).

Brodeck et al disclose a viscous gel vehicle comprising a biocompatible polymer, a mixture of solvents and a bioactive (see Abstract; page 13, lines 1-6). The mixture itself may comprise hydrophobic and hydrophilic solvents in admixture so as to form a solvent with a water solubility of less than 1 wt % (see page 24, lines 20-210). The viscosity of the gel may be less than 1000 centipoise (see page 3, line 6). The solvent mixture is more specifically defined as a mixture of hydrophilic solvent (Which can be up to 50 wt % and a hydrophobic solvent. Benzyl benzoate is specifically recited as the hydrophobic solvent and can be found at concentrations of greater than 50% or 80 % (see page 28, lines 1-23).The beneficial agent can be found at a concentration of between 1 and 50% at page 4, lines 7-8. The concentration of the beneficial agent can be up to 100 mg/ml. (see page 51, lines 12 and 14). Release of the bioactive within the first 24 hrs is 20% or less (see page 2, lines 17-21). The bioactive may be dispersed or dissolved in the gel as shown at page 11, line 8 , as well as throughout the specification. Viscosity of the gel is found at page 37, line 6. The particular combination of solvents, polymers and

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bioactives may be found at page 28, lines 1-2; page 23, lines 3-24; page 24, lines 1-5; page 41, lines 3-24; page 42, lines 1-24; page 43, lines 1-24; page 44, lines 1-24; page 45, lines 1-11. The claimed method differs only in the gauge of the needle used to administer the gel. However, adjustment of the viscosity for other methods of administration is taught at page 37, lines 13 -19. Therefore, those of ordinary skill would have found it well within their ability to adjust the pH according to whatever gauge needle was being used according to the teachings of Brodeck et al. The instant claims would have therefore been obvious to one of ordinary skill in the art at the time of invention given the teachings of Brodeck et al.

Claims 4, 15, 55, 64, 65, 82 and 83 are objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

caz

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